UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA
and THE STATE OF FLORIDA ex
rel. CHRISTINA PAUL

Plaintiffs/Relator,

v. Case No: 8:18-cv-396-T-36JSS

BIOTRONIK, INC.,

Defendant.
_____/

ORDER

This matter comes before the Court upon Defendant Biotronik Inc.'s Motion to Dismiss the Second Amended Complaint and Supporting Memorandum of Law [Doc. 50], Plaintiffs/ Relator's Response in Opposition [Doc. 53], and Defendant's Reply to Plaintiff's Opposition [Doc. 57]. The Court, having considered the motion, will GRANT Defendant's Motion to Dismiss for the reasons stated herein.

I. BACKGROUND AND FACTS[1]

Defendant, Biotronik, is a medical device company with products and services related to patients suffering from cardiovascular and endovascular diseases. [Doc. 49 ¶ 5]. Relator, Christina Paul, was an employee of Biotronik, from April 7, 2014 until

[1] The following statement of facts is derived from Relator's Second Amended Complaint (Doc. 49), the allegations of which the Court must accept as true in ruling on the instant Motion to Dismiss. *See Linder v. Portocarrero*, 963 F.2d 332, 334 (11th Cir. 1992); *Quality Foods de Centro Am., S.A. v. Latin Am. Agribusiness Dev. Corp. S.A.*, 711 F. 2d 989, 994 (11th Cir. 1983).

June 2019. *Id.* ¶ 4. During that time, she worked as a Field Clinical Specialist, then as a Diagnostic Specialist *Id.* In both of her positions, Relator provided technical and clinical support to some of Defendant's sales staff. *Id.* Since at least April of 2014, Defendant has allegedly generated consumer demand for its services and devices through a fraudulent scheme in which it induces medical professionals to use its products and services through illegal incentives it pays, in violation of the federal anti-kickback statute. *Id.* ¶ 18.

Relator specifically alleges that from 2014 through June 2019, Defendant's employee, Paul McLoughlin, with Defendant's knowledge, provided incentives—including vacations and trips, meals, payments for cell phone bills, entertainment, holiday gifts, grand opening expenses, parties, marketing events, and donations—to referral sources and to physicians in exchange for their use of its services and products. *Id.* ¶¶ 19, 21. Relator identifies eleven physicians who were involved in this scheme: Dr. Ketul Chauhan; Dr. Rajesh Lall; Dr. Aung Tun; Dr. Ramanath Rao; Dr. Phillip Owen; Dr. Osama Al-Suleiman; Dr. Binu Jacob; Dr. Oji Joseph; Dr. Luis Carillo; Dr. Siva Bhashyam; and Dr. Irfan Siddiqui. *Id.* ¶¶ 22-31. Relator alleges she witnessed the illegal procuring of these clients. *Id.* ¶ 32.

Through this fraudulent scheme, Defendant allegedly gained market share and increased its profits in the form of an average $3,000 for each loop device, $7,000 for each pacemaker, $13,500 for each defibrillator, and $26,000 for each biventricular defibrillator. *Id.* ¶ 33. Defendant charged Medicare, Medicaid, and other Government-funded healthcare programs an additional $500-1,000 per implanted device under the

guise of a home monitoring program that was not ordered by the physicians, was not consented to by the patients, and never occurred. *Id.* ¶ 34. Relator provided a list of eighty-five patients who were improperly placed on home monitoring or implanted with Defendant's products as a result of Defendant's kickback scheme. *Id.* ¶ 44.

Relator specifically alleges that McLoughlin was authorized by Defendant to set up and bill to Medicare and Medicaid home monitoring services for patients without the approval of the attending physicians. *Id.* ¶ 35. For example, in June 2017 McLoughlin set up home monitoring services for several of Dr. Ahmed's patients, despite the doctor's refusal, and billed these services to Medicare and Medicaid. *Id.* ¶¶ 36-37. On August 23, 2017, Dr. Ahmed's nurse, Ursula Morrow, contacted Relator advising that Dr. Ahmed's patients were coming into the clinic with home monitoring devices and asking what needed to be done. *Id.* ¶ 38. Ms. Morrow told Relator that neither she nor Dr. Ahmed knew about or had access to the home monitoring accounts, and requested an explanation. *Id.* Relator reported this to Defendant's Home Monitoring Department Management Representative, John Fitzke, in August 2017.[2] *Id.* ¶¶ 40-41. Defendant never took any steps to remedy the Home Monitoring issue or address the misconduct reported by Relator, and its Vice President of Regulatory Affairs subsequently instructed all employees not to put conversations with physicians or among staff in writing, and warned employees written communications could be subject to subpoena. *Id.* at ¶¶ 42-43, 46.

[2] Relator's August 25, 2017 letter to Defendant regarding the home monitoring practices taking place within Dr. Ahmed's practice is provided with the complaint.

On May 14, 2020, Relator filed a Second Amended Complaint[3] against Defendant, asserting claims under the federal False Claims Act, 31 U.S.C. § 3729, and Florida's False Claims Act, § 68.082(2)(a), Fla. Stat. [Doc. 49]. Defendant has again moved to dismiss for failure to state a claim and failure to meet the heightened pleading requirements for fraud claims. [Doc. 50]. Among other things, it argues that the complaint does not sufficiently plead a kickback scheme; does not provide particular facts about fraudulent submissions to the government; fails to state which federal programs received and paid the claims; fails to identify any payment obligation Defendant had to the government; and does not allege a causal connection between Defendant's action and the submission of any false claim. *Id.* at pp. 7-15. Relator contends that the Second Amended Complaint satisfies all of the requirements identified by the Court in the order dismissing the original complaint and is sufficient to meet the necessary pleading standard for causes of action under the False Claims Acts. [Doc. 53].

II. LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), a pleading must include a "short and plain statement of the claim showing that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009) (quoting Fed. R. Civ. P. 8(a)(2)). Labels,

[3] This lawsuit was originally filed on February 15, 2018. [Doc. 1]. Both the United States and the State of Florida declined intervention. [Docs. 18, 27]. Defendant moved to dismiss the complaint for failure to state a claim and failure to meet the heightened pleading requirements for fraud claims and the motion was granted with leave to amend the complaint. [Docs. 26, 45].

conclusions and formulaic recitations of the elements of a cause of action are not sufficient. *Id*. (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Furthermore, mere naked assertions are not sufficient. *Id*. A complaint must contain sufficient factual matter, which, if accepted as true, would "state a claim to relief that is plausible on its face." *Id*. (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citation omitted). The court, however, is not bound to accept as true a legal conclusion stated as a "factual allegation" in the complaint. *Id*.

Additionally, Federal Rule of Civil Procedure 9(b) places more stringent pleading requirements on claims alleging fraud. Fed. R. Civ. P. 9(b). "[U]nder Rule 9(b) allegations of fraud must include facts as to time, place, and substance of the defendant's alleged fraud." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1308 (11th Cir. 2002) (citation and internal quotations omitted). Plaintiffs are thereby required to set forth "the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009) (internal quotation marks omitted) (citing *Clausen*, 290 F.3d at 1310). Failure to satisfy the particularity requirement under Rule 9(b) amounts to failure to state a claim until Rule 12(b)(6). *See, e.g., Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005).

III. DISCUSSION

Relator has alleged federal and Florida False Claims Act violations arising from an alleged unlawful kickback scheme between Defendant and eleven doctors. [Doc. 49 at ¶¶ 22, 48-81]. The False Claims Act, 31 U.S.C. § 3729 et seq., imposes civil liability on "any person who … knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the federal government or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1284 (11th Cir. 2019) (quoting 31 U.S.C. § 3729(a)(1)(A)–(B)). It also "imposes liability on any person who knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government[.]" *U.S. ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1221–22 (11th Cir. 2012). "Florida has . . . a parallel statutory scheme with similar provisions." *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1272 (11th Cir. 2018) (citing Fla. Stat. §§ 68.082(2)(a), (b), (g); 68.083(2)).[4] The Act "serves as a mechanism by which the Government may police noncompliance with Medicare reimbursement standards after payment has been made." *AseraCare, Inc.*, 938 F.3d at 1284.

[4] "Because the Florida False Claims Act is modeled after the Federal False Claims act, the claims will be analyzed using the same general standards." *United States ex rel. Watine v. Cypres Health Sys. Fla., Inc.*, No. 1:09-cv-0137-SPM-GRJ, 2012 WL 467894, and *1 (N.D. Fla. Feb. 14, 2012). Claims brought under Florida's False Claims Act require proof of the same elements as its federal counterpart. *United States v. Sand Lake Cancer Ctr., P.A.*, No. 8:13-CV-2724-T-27MAP, 2019 WL 423156, at *2 (M.D. Fla. Feb. 4, 2019).

A. The Kickback Scheme

As an initial matter, Defendant contends, and the Court agrees that Relator has not sufficiently pleaded that Defendant was engaged in a kickback scheme with any of the eleven doctors or any referral source. [Doc. 50 at p. 4]. The Eleventh Circuit explained in *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1272 (11th Cir. 2018) that

> The Anti-Kickback Statute creates liability for anyone who "knowingly and willfully offers or pays any remuneration … to any person to induce such person … *to refer an individual* to a person for the furnishing … of any item or service for which payment may be made in whole or in part under a Federal health care program." *Id.* § 1320a-7b(b)

(citing 42 U.S.C. § 1320a-7b(b)(2)). The statute "broadly forbids kickbacks, bribes, and rebates in the administration of government healthcare programs." *Id.* A violation of the statute occurs when the defendant (1) knowingly and wilfully, (2) pays money, directly or indirectly, to doctors, (3) *to induce the doctors to refer individuals* to the defendants for the furnishing of medical services, (4) paid for by a Federal health care program. *U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 698 (11th Cir. 2014) (citing *United States v. Vernon,* 723 F.3d 1234, 1252 (11th Cir. 2013)).

The complaint does not sufficiently plead the who, what, when, or how as to the payment of money, directly, or indirectly, to the doctors identified nor any referral source. The complaint is deficient as to when the alleged payments occurred. Relator alleges generally that "[t]he practices referenced herein occurred from 2014 through the June 2019." [Doc. 49 ¶ 21]. That is not enough. Relator also provided specific dates

or periods as to some acts, for example, the purchase of custom "Boxed cookies" on December 9, 2015 to give to Dr. Bhashyam as Christmas cookies so that he could use them as referral physician gifts. *Id.* ¶ 30. But still, Relator does not allege when these cookies were actually given to Dr. Bhashyam, which is the relevant time for purposes of alleging the scheme. *See Sampson v. Washington Mut. Bank*, 453 F. App'x 863, 866 (11th Cir. 2011) ("Because Sampson fails to allege in his complaint who made the misrepresentations, what their precise content was, when they were made, and where they were made, he has not set forth facts sufficient to plead fraud."); *United States ex rel. Silva v. VICI Mktg., LLC*, 361 F. Supp. 3d 1245, 1254 (M.D. Fla. 2019) (denying dismissal of count against Z Stat Medical and reasoning that "[t]he Complaint in partial intervention . . . describes how Z Stat Medical maintained spreadsheets outlining the kickbacks due under each kickback scheme. The United States pled the dates and amounts of various kickback payments paid through Z Stat Medical and the details of some representative false claims. Thus, there are sufficient allegations about Z Stat Medical individually to support the FCA claim.") (docket cites omitted). Allegations as to purported payments to some doctors were entirely devoid of a date the payment was made. *See, e.g., id.* ¶¶ 22(a),(c),(d),(e),(f). Because of the lack of particularity, none of the allegations as to payment is sufficient for purposes of Rule 9(B), such that the Court must find that Relator has not met the heightened standard for pleading a kickback scheme.

B. The False Claims Counts

Even if Relator had sufficiently alleged a kickback scheme, the complaint suffers additional deficiencies in pleading the counts asserted, which warrant dismissal of the complaint.

> To establish a cause of action under § 3729(a)(1)(A), a relator must prove three elements: (1) a false or fraudulent claim, (2) which was presented, or caused to be presented, for payment or approval, (3) with the knowledge that the claim was false. 31 U.S.C. § 3729(a)(1)(A). To prove a claim under § 3729(a)(1)(B), a relator must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim. 31 U.S.C. § 3729(a)(1)(B).

United States ex rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1154 (11th Cir. 2017). To establish a reverse false claim, pursuant to 31 U.S.C. § 3729(a)(1)(G), a relator must prove: (1) a false record or statement; (2) the defendant's knowledge of the falsity; (3) that the defendant made, used, or causes to be made or used a false statement or record; (4) for the purpose to conceal, avoid, or decrease an obligation to pay money to the government; and (5) the materiality of the misrepresentation. *Medco Health Sols., Inc.*, 671 F.3d at 1222. Again, claims brought under Florida's False Claims Act require proof of the same elements as its federal counterpart. *United States v. Sand Lake Cancer Ctr., P.A.*, No. 8:13- CV-2724-T-27MAP, 2019 WL 423156, at *2 (M.D. Fla. Feb. 4, 2019). The Court will address an additional deficiency that is fatal as to each count.

i. Presentment of False Claims

Count I alleges a claim pursuant to § 3729(a)(1)(A) and Count IV alleges the corresponding claim under Florida law. As noted in the Court's prior order, "[t]he submission of a claim is . . . the *sine qua non* of a False Claims Act violation." *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002). "The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." *Id.* "To satisfy the presentment requirement, a relator 'must allege the actual presentment of a claim … with particularity, meaning particular facts about the who, what, where, when, and how of fraudulent submissions to the government.' " *United States v. Choudhry*, 262 F. Supp. 3d 1299, 1308-09 (M.D. Fla. 2017) (quoting *Urquilla–Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1052 (11th Cir. 2015)).

Failure to sufficiently plead that a claim was submitted justifies dismissal of a claim alleging a violation of § 3729(a)(1)(A). In *Clausen*, for example, the district court found that the First Amended Complaint's failure to identify any specific claims that were submitted to the United States or identify the dates on which those claims were presented to the government was a fatal flaw and that the Second Amended Complaint's addition of conclusory statements that LabCorp submitted for specified tests on the "date of service or within a few days thereafter," suffered from the same defect. *Clausen*, 290 F.3d at 1311. The appellate court agreed, finding that the allegations in the Second Amended Complaint were conclusory and reasoning that

"[i]f Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion." *Id.* at 1311, 1313. As in this case, Clausen provided patient identities, dates of testing and testing procedures, but without information about claims actually submitted, the appellate court held that dismissal was proper. *Id.* at 1313-15.

The Court acknowledges, as Relator points out in her response, that she has provided eighty-five examples of patients implanted with Defendant's products and/or placed on home monitoring as a result of the alleged kickback scheme—including information as to dates, products used, procedures performed, invoice numbers, insurance entities, as well as which doctors performed the procedures. [Doc. 53 pp. 6, 10]. As to each patient, Relator alleges that "[t]hese medical devices, services, and procedures were ultimately paid for by Medicare, Medicaid, or another government funded healthcare provider." [Doc. 49, ¶ 44(a-cg)]. It is not sufficient for Relator to allege merely that claims must have been submitted, were likely submitted, or should have been submitted to a federally-funded healthcare provider. *U.S. ex rel. Clausen*, 290 F.3d 1311. Without providing certain details such as dates that false claims were submitted, amounts listed in those claims, or similar details, a complaint does not meet the standards of Fed. R. Civ. P. 9(b). *Sanchez*, 596 F.3d at 1302. This is the case here as Relator fails to identify any claims submitted for payment to a government funded healthcare provider as a result of Defendant's alleged kickback scheme. She has provided the "who," "what," "where," "when," and "how" of improper practices, but has failed to allege the "who," "what," "where," "when," and "how" of fraudulent

submissions to the government. *Corsello*, 428 F.3d at 1014. Moreover, while it is true that personal knowledge—as a result of employment or conversations with billing employees—can provide support for an FCA complaint, *Unites States ex rel. Walker v. R&F Properties of Lake Cnty. Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005), no such allegation is presented here and the Court cannot find the indicia of reliability that could otherwise cure any deficiency as to the sufficiency of the allegations. See *United States v. HPC Healthcare, Inc.*, 723 F. App'x 783, 789 (11th Cir. 2018) ("[T]his Court has deemed indicia of reliability sufficient where the relator alleged direct knowledge of the defendants' submission of false claims based on her own experiences and on information she learned in the course of her employment."). As a result, Relator has not sufficiently pleaded a claim that Defendant presented or caused to be presented to a federal healthcare program, a false or fraudulent claim for payment, which further warrants dismissal of Counts I and IV.

ii. False Record or Statement

Counts II and V both allege that Defendant made, used, or caused to be made or used false or fraudulent records and statements to get a false claim paid or approved by the government. [Doc. 49]. Defendant argues, among other things, the complaint fails to allege any false statement or record made or caused to be made by Defendant. [Doc. 50 pp. 2, 11]. In response, relator contends that she has described in detail how Defendant used dummy home monitoring sites to create a false record that patients had been monitored. [Doc. 53 at p. 11]. The Court has reviewed the allegations of the

complaint, and specifically those cited by Relator in her response, and finds that they too, are conclusory.

Relator alleges that Defendant was billing for home monitoring of patients that was never ordered by the physician, never consented to by the patient and never occurred, and that home monitoring accounts were not being used. [Doc. 49 §¶¶ 34-39, 44]. Additionally, she alleges that Defendant engaged in a practice of creating dummy accounts. *Id.* Importantly, Relator has not identified any specific statement or record. This Court has previously dismissed complaints for this very reason. *See United States ex rel. McFarland v. Fla. Pharmacy Sols.*, 358 F. Supp. 3d 1316, 1330 (M.D. Fla. 2017) (dismissing false statement count for lack of particularity and reasoning that "McFarland attaches, for example, no false statement or record to the complaint and fails to identify the date of any statement or record."). The Court recognizes that Relator provided some specifics as to Dr. Ahmed, but finds that she has still not alleged the how, what, or other relevant details regarding the claimed fraudulent billing or use of dummy accounts, which is required when pleading fraud. *See United States ex rel. Stepe v. RS Compounding LLC*, 304 F. Supp. 3d 1216, 1225 (M.D. Fla. 2018) ("To the extent the Court can divine what false records or statements Stepe intended to reference in this count, the Court finds those statements insufficiently pled under Rule 9(b). Stepe still has not sufficiently pled how the pre-printed script pads specifying a high refill number constitute a false statement, given that physicians are free to mark out the default refill number and fill in another."). As such, the Court finds that Relator

has not met the heightened standard of pleading as to the claims alleged in Counts II and V.

iii. Obligation to the Government

The Court agrees with Defendant that Relator has not adequately pleaded a reverse false claim pursuant § 3729(a)(1)(G). "[L]iability [under that section] results from avoiding the payment of money due to the government, as opposed to submitting to the government a false claim." *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012) (citing *United States v. Pemco Aeroplex, Inc.,* 195 F.3d 1234, 1235–36 (11th Cir.1999)); *United States ex rel. Stepe v. RS Compounding LLC*, 304 F. Supp. 3d 1216, 1226 (M.D. Fla. 2018) (same). Relator has not sufficiently pleaded that Defendant had a payment obligation to the government. As Defendant contends, nowhere in the Amended Complaint does Relator plead with particularity any overpayments to Defendant based on false submissions, which in turn created an obligation to refund the government. Instead, Relator provides conclusory allegations that Defendant's kickback scheme allowed it to collect money it was not entitled to and that by concealing this scheme Defendant has denied the government the ability to demand a return of the money. [Doc. 49 ¶¶ 59-61, 78-79. In fact, Relator has only generally alleged throughout the complaint that the patient's procedures were believed to have been paid out by Medicare, Medicaid, or another government funded healthcare provide. *Id.* ¶ 37, 44. This is not enough to serve as the basis of an obligation to the government for purposes of reverse false claim liability. Counts III and VI are therefore also subject to dismissal on this basis.

C. Leave to Amend

Finally, the parties raise an issue as to whether the dismissal should be granted with prejudice or whether Relator should be allowed to file an amended complaint. "[A] district court's discretion to dismiss a complaint without leave to amend is 'severely restrict[ed]' by Fed. R. Civ. P. 15(a), which directs that leave to amend 'shall be freely given when justice so requires.' " *Thomas v. Town of Davie*, 847 F.2d 771, 773 (11th Cir. 1988) (quoting *Dussouy v. Gulf Coast Investment Corp.,* 660 F.2d 594, 597 (Former 5th Cir.1981)). "In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be 'freely given.' " *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1270 (11th Cir. 2006) (quoting *Foman v. Davis,* 371 U.S. 178, 182 (1962)). Nothing on the record in this case suggests undue delay, bad faith, or dilatory motive on the part of Relator, nor that Defendant will be unduly prejudiced if the Court allows Relator to amend the complaint. Additionally, the Court finds that a more carefully drafted complaint could sufficiently state a claim. Therefore, the Court will allow Relator one final opportunity to amend her complaint.

Accordingly, it is hereby **ORDERED**:

1. Defendant's Motion to Dismiss [Doc.50], is GRANTED. Relator is granted leave to file a Third Amended Complaint on or before **February**

4, 2021, which cures the deficiencies discussed in this and the previous Order. Failure to file the amended complaint within the time provided will result in dismissal of this action without further notice.

DONE AND ORDERED in Tampa, Florida on January 21, 2021.

Charlene Edwards Honeywell

Charlene Edwards Honeywell
United States District Judge

Copies to:
Counsel of Record and Unrepresented Parties, if any